K130184

MAY 2 4 2013

5 510 (k) Summary

Submitter of 510(k): Wieland Dental + Technik GmbH & Co. KG
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Date of Summary: 2013-01-19

Trade name: Zenolux

Common name: Dental ceramic
Classification name: Powder, Porcelain
Product code: EIH
C.D.R section: 872.6660
Classification: Class II

Legally marketed equivalent device: (510(k) number)
ZENO Al eco Disc (K082257)
inCoris AL (K062506)
Procera Bridge Alumina (K053050)

Cercon ht (K112152)
Zenostar Zr Translucent (K112710)

510 (k) Summary

Device description

Zenolux is a discoidal shaped, pre- sintered dental ceramic material that is composed of pure aluminium oxide (> 99,5%).

It is a ready- to-use milling blank, which has to be processed in a milling machine with the CAD/CAM technology to achieve the desired shape. Thereafter, the milled unit has to be sintered at high temperatures (about 1350°C) to attain its nominal density and final chemical, physical and biological properties, which ensure its excellent effectiveness and safety, as well as its pleasant aesthetical translucency. Sintered Zenolux material is biocompatible, insoluble in water and have high flexural strength.
To achieve a natural and individual tooth color, Zenolux restorations can be veneered with suitable dental porcelains or simply stained and glazed, for example with Allux (K050302),

Zenolux meets all applicable requirements of the standard ISO 6872: 2008 "Dentistry – Ceramic materials", and exceeds the thresholds for a Type II, class 5 dental ceramic by far.

Zenolux encompasses diverse models, which have a diameter of about 60 mm and thicknesses from 10 mm up to 25 mm.

Indications for use

Zenolux is intended to be used by professional dental technicians for the CAD/CAM-fabrication of all-ceramic dental restorations for the sole use of a particular patient. It is recommended for manufacturing single crowns and three-unit bridges, which can be applied in the anterior as well as in the posterior tooth region.
Zenolux units can be used as frameworks for veneering with suitable dental porcelain and/or as monolithic, full-contour restorations, as well.

Comparison with the predicate device

Zenolux is substantially equivalent to the dental devices Zeno Al eco Disc (K082257), inCoris AL (K062506) and Procera Bridge Alumina (K053050).
There is no difference in fundamental scientific technology between these predicates and Zenolux. Similarly, the technological characteristics of Zenolux are identical or even better than those of the predicates. All devices based on pure Aluminium oxide, have to be processed by CAD/CAM technology and to be densely sintered at high temperatures to attain its final properties. The main difference is the extended indication for use including posterior bridges and the use as full -contour crown or bridges.

Bench testing of the characteristics according to ISO 6872:2008 indicate extremely low water solubility and high biocompatibility of the Zenolux material. Mechanical strength (flexural strength) of Zenolux is even better compared to the predicate devices, and exceeds the threshold of a class 5 ceramic, which is suitable for three-unit prostheses involving molar restoration, by far.

Regarding its application as full-contour restoration it is substantially equivalent to the dental devices Cercon ht (K112152) and Zenostar Zr Translucent (K112710) Wear tests showed that the abrasion of the Zenolux -material itself (not veneered) and of the antagonist teeth opposed to the material is similar to the predicate materials and lower compared to conventional veneering porcelain.

The fit of 3-unit Zenolux bridges is excellent and identical to that of other clinically approved CAD/CAM – materials, like zirconia.

Animal or clinical testing were not performed.

Conclusion
The chemical composition of Zenolux, its fundamental scientific technology and its technological characteristics are the same as in the predicate devices. The substantial equivalence of the indications for use has been proven by bench tests and professional evaluations. Therefore Zenolux is substantial equivalent in safety and effectiveness to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 24, 2013

Gerhard Polzer, Ph.D.
Director, Regulatory Affairs
Wieland Dental + Technik GmbH & Co. KG
Schwenninger Strasse 13
D-75179 Pforzheim
GERMANY

Re: K130184
Trade/Device Name: Zenolux
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: March 22, 2013
Received: March 28, 2013

Dear Dr.Polzer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Digitally signed by Mary S. Runner -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Mary S. Runner -S, 0.9.2342.19200300.100.1.1=1300087950
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Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

22.7 Indication for use statement

Indications for Use

510(k) Number (if known): K130184

Device Name: **Zenolux**

Indications for Use:

Zenolux are milling blanks, which are intended to be used by professional dental technicians for the CAD/ CAM –fabrication of all-ceramic crowns and 3-unit bridges, in the anterior as well as posterior tooth region. These parts can be used as framework for veneering with suitable dental porcelain and/ or as full-contour monolithic restorations.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner, DDS, MA

Digitally signed by Mary S. Runner -S
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Date: 2013.05.24 15:16:45 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: _____